REMARKS

Claims 1 and 3-38 are pending. Independent Claim 1 has been amended to incorporate the water-soluble polymer limitations of Claim 2 (the elected species of permeation control layer is poly(vinyl alcohol), which is a water-soluble polymer as described in the specification at page 4, lines 20-28). Claim 1 has also been amended to limit the layer of adhesive to an acrylic adhesive and/or a rubber-type adhesive and to limit the medicine storage layer to a solid. Support for acrylic adhesive and/or a rubber-type adhesives is found in the specification between line 2 from the bottom of page 6-page 7, line 1 of the specification.

Descriptive support for solid medicine storage layers is implicit throughout the specification and solid medicine storage layers are exemplified, for instance, in Example 1 on page 9, second full paragraph, of the specification.

New Claim 38 is directed to the specific combination of poly(vinyl alcohol) and nicorandil, which the previous Official Action indicated would be allowable. Support for Claim 38 is found on lines 9-10 from the bottom of page 3 of the specification. Accordingly, the Applicants do not believe that any new matter has been added.

The Applicants thank Examiner Sheikh for the helpful discussion of April 24, 2003 and thank Examiners Sheikh and Kishore for the courteous discussion on May 28, 2003. The differences between the invention and the liquid and solid reservoir devices of Figs. 3 and 4 of Pfister et al., U.S. Patent 5,232,702, were discussed. It was suggested that limitations to particular adhesives might address the anticipation rejection based on Pfister et al. and that a limitation to a solid medicine storage layer, as exemplified, for instance, in Example 1 on page 9 of the specification, might help distinguish over the devices shown in Fig. 3 of Pfister

et al., which contain a liquid medicine storage reservoir. These limitations are now presented in independent Claims 1 and 38.

The Applicants also pointed out the differences between the solid reservoir device of Pfister et al, Fig. 4. Briefly, while the solid reservoir device in Fig. 4 of Pfister et al., may optionally contain a "rate-controlling membrane", Pfsiter et al. does not describe a permeation controlling film made out of a water soluble polymer, nor does it suggest using or selecting the permeation controlling film of the present invention that is plasticized when activated by moisture from the skin and that permits the permeation of the medicine(s) out of the medicine storage layer when plasticized. It was also suggested that a claim directed to the combination of poly(vinyl alcohol) and nicorandil be presented. The claims have now been amended in view of the Examiners' suggestions and to further clarify particular aspects of the invention. Favorable consideration is respectfully requested.

Rejection -- 35 U.S.C. 102

Claims 1, 4-6, 19, 20 and 32-36 were rejected under 35 U.S.C. 102(b) as being anticipated by Pfister et al., U.S. Patent 5,232,702. Pfister does not anticipate the elected species of invention, because it does not disclose nicorandil. Moreover, it does not anticipate the claims because it does not disclose an acrylic adhesive or a rubber-based adhesive as now required by Claim 1. The adhesives in Pfister are silicon-based adhesives, see e.g., Pfister, the Title, Abstract and col. 3, starting at line 7.

Pfister also does not disclose all the elements of the invention. For instance, it does not disclose a solid medicine storage layer in combination with a permeation controlling film, which when activated by moisture, allows the medicines to permeate, dissolve, disperse or diffuse through the permeation controlling film into the skin. To further distinguish this

aspect of the invention from Pfister, Fig. 3, Claim 1 has been amended to indicate that the medicine storage layer is solid.

Moreover, the solid reservoir device of Pfister, Fig. 4, is not disclosed as containing a permeation controlling film, which is a water soluble polymer that is plasticized when activated by moisture as required by Claims 1 and 38. Pfister is directed to rate controlling membranes and not to a permeation controlling film as required by the invention. Even were the permeation controlling film of the present invention one type of a rate controlling membrane, one would not immediately envisage the water soluble polymer permeation controlling film of Claims 1 and 38 from the generically described rate controlling membrane of Pfister. Similarly, one would not immediately envisage from Pfister a rate controlling membrane that plasticizes when activated by moisture from the skin and then allows medicine to flow. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

Rejection -- 35 U.S.C. 103

Claims 1, 4-9, 19, 20 and 32-37 were rejected under 35 U.S.C. 103(a) as being unpatentable over Pfister et al., U.S. Patent 5,232,702, in view of Mantelle, U.S. Patent 5,446,070. The cited prior art does not render the invention obvious, because it does not disclose or suggest the present invention.

First, neither Pfister nor Mantelle disclose the acrylic or rubber-type adhesives as now required by independent Claim 1.

Second, neither Pfister nor Mantelle disclose or suggest the combination of a solid medicine storage layer and a permeation controlling film, which is a water soluble polymer,

that is plasticized when activated by moisture from the skin and that permits the permeation of medicine in the medicine storage layer.

Claims 1 and 38, as amended to refer to solid medicine storage layers, and are distinguishable from the device shown in Fig. 3 of Pfister which contains medicine in a liquid reservoir. Col. 8, lines 55-58, of Pfister described a rate controlling membrane in conjunction with the liquid reservoir device of Fig. 3:

> This membrane acts as the rate controlling mechanism for the delivery of the liquid drug(s), co-solvents, enhancers and excipients, from the reservoir 34.

However, there is no disclosure of, or suggestion, for a permeation controlling film or rate controlling membrane that is a water soluble polymer, nor for a permeation controlling film that is activated by moisture from the skin.

The solid reservoir device shown in Fig. 4 of Pfister may optionally contain a "rate controlling membrane" (col. 9, lines 15-16):

> An additional layer (not shown) comprising a rate controlling membrane may be positioned between the solid reservoir 54 and the adhesive 58 in order to control the rate of delivery of the drug(s), and excipient(s).

However, there is no suggestion in Pfister to select the permeation controlling film of the present invention. First, Pfister does not disclose a permeation controlling film or rate controlling membrane which is a water soluble polymer. Second, there is no suggestion in Pfister to select a permeation controlling film that allows the medicine within a solid medicine storage layer to permeate, dissolve, disperse or diffuse into the skin when the film is exposed to moisture from the skin. Moreover, Pfister does not disclose the acrylic or rubber-based adhesives of the present invention. Accordingly, Pfister by itself cannot render the invention obvious.

Mantelle refers to a large variety of drug compounds (cols. 23-41), including nicorandil (col. 41, line 17) and various adhesives (col. 12, starting at line 54), but does not remedy the deficiencies of Pfister. That is, this document does not suggest a device having a solid medicine storage layer in combination with water soluble polymer permeation controlling film, nor does it suggest that a medicine, such as nicorandil would "permeate, dissolve, disperse or diffuse into a plasticized permeation controlling film which has been activated by moisture" as required by the present invention. Moreover, in Mantelle, see e.g., col. 12, lines 101-5, the active agent is added to an adhesive prior to being placed on a flexible form or backing. On the other hand, the present invention comprises a separate medicine storage layer, permeation controlling film and adhesive layer, see Claim 1. The present invention permits the controlled release of the medicine in the storage layer after the permeation controlling film is contacted with moisture from the skin.

Therefore, the cited prior art does not render the invention obvious, because (1) it does not disclose a permeation controlling film which is a water soluble polymer, (2) provides no suggestion to select a permeation controlling film that is plasticized when activated by moisture from the skin, and (3) does not suggest that medicines like nicorandil would permeate, dissolve, disperse or diffuse into a plasticized permeation controlling film. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

Conclusion

In view of the above amendments and remarks, the Applicants respectfully submit that this application is now in condition for allowance. Early notification to that effect is earnestly solicited.

Respectfully submitted,

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MARKED UP COPY OF AMENDMENT

IN THE CLAIMS

Cancel Claim 2.

Please amend Claims 1 and 36 as follows:

--1. (Twice amended) A composition comprising:

a supporting body,

a solid medicine storage layer comprising one or more medicine(s) that permeate, dissolve, disperse or diffuse into a plasticized permeation controlling film which has been activated by moisture,

a permeation controlling film, which is a water soluble polymer, that is plasticized when activated by moisture from the skin and that permits the permeation of the medicine(s) out of the medicine storage layer when plasticized,

[a layer of an adhesive] a layer of an adhesive comprising an acrylic adhesive and/or a rubber type adhesive, and

a release liner.--

--2. (Cancelled)

--36. (Amended) A method for making the composition of claim 1 comprising:

attaching or laminating together:

a supporting body,

a solid medicine storage layer comprising one or more percutaneously absorbable medicine(s) that permeate, dissolve, disperse or diffuse into a plasticized permeation controlling film which has been activated by moisture,

a permeation controlling film that is plasticized when activated by moisture from the skin and that permits the permeation of the medicine(s) out of the medicine storage layer when plasticized,

a layer of an adhesive and

a release liner--

Add new Claim 38.

--38. (New)--